Prevaccination Checklist for COVID-19 Vaccines

Information for Healthcare Professionals

The following guidance should be used to determine if COVID-19 vaccine can be administered or not, based on the recipients answers to checklist questions. Using the completed prevacciantion checklist, review clinical guidance based on the answers to the questions. Use this document in conjunction with:

- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States at www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
- Advisory Committee on Immunization Practices on Immunization General Best Practice Guidelines at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

COVID-19 vaccines are authorized and approved for different age groups and are given intramuscularly.

COVID-19 Vaccine Product	Pfizer-BioNTech		Moderna	Janssen*
	Orange Cap	Gray Cap Purple Cap		
Age Indications	5 through 11 years of age	12 years and older	18 years and older	18 years and older

* **Note:** mRNA vaccines (Moderna, Pfizer-BioNTech) are preferred over Janssen COVID-19 Vaccine.

For guidance on specific schedules, storage, preparation, and administration, please see:

- Interim COVID-19 Immunization Schedule for Ages 5 Years and Older at www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-5yrs-older.pdf
- COVID-19 Vaccination Clinical & Professional Resources for each vaccine product at www.cdc.gov/vaccines/covid-19/info-by-product/index.html

Postvaccination Observation Times for People without Contraindications to COVID-19 Vaccination

30 minutes:

- People with a history of:
  - Contraindication to another type of COVID-19 vaccine product due to allergy
  - Immediate (within 4 hours of exposure) non-severe allergic reaction to other (non-COVID-19 vaccines) or injectable therapies.
  - Anaphylaxis due to any cause
  - Non-severe allergic reaction to a previous dose of that same type of COVID-19 vaccine

15 minutes:

- All other people
  - If first dose, 15 minute observation period recommended.
  - If not the first dose, 15 minute observation period may be considered

Co-administration of COVID-19 vaccines and other vaccines

COVID-19 vaccines and other vaccines **may be administered without regard to timing.** This includes simultaneous administration of COVID-19 vaccines and other vaccines during the same visit. Other vaccines can also be administered anytime before or after COVID-19 vaccination.

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1. Are you feeling sick today?

While there is no evidence acute illness reduces vaccine efficacy or increases adverse reactions, as a precaution, **delay vaccinating patients with moderate or severe illness** until the illness has improved.

Defer vaccination of people with current SARS-CoV-2 infection until the person has recovered from acute illness and has discontinued isolation. This recommendation applies regardless of whether the SARS-CoV-2 infection occurred before the recipient received an initial dose or between doses. Viral or serological testing to assess for current or prior infection solely for the purpose of vaccine-decision making is not recommended.

People with mild illnesses can be vaccinated. Do not withhold vaccination if a person is taking antibiotics.

2. Have you ever received a dose of COVID-19 vaccine?

VACCINE PRODUCT	Primary Series Dosage (Amount)	Booster Dosage (Amount)
Pfizer-BioNTech COVID-19 Vaccine *(Orange Cap)* 5 through 11 years of age	0.2 mL	N/A
Pfizer-BioNTech COVID-19 Vaccine *(Purple Cap or Gray Cap)* 12 years of age and older	0.3 mL	0.3 mL
Moderna COVID-19 Vaccine	0.5 mL	0.25 mL
Janssen COVID-19 Vaccine (Johnson & Johnson)	0.5 mL	0.5 mL

People 5 years of age and older **should** receive a primary series of COVID-19 vaccine. All COVID-19 primary series doses and additional primary doses should be the same vaccine product. Booster doses, for eligible persons, may be a different product than the COVID-19 vaccine product used in the primary series (e.g., mix and match may be used for boosters).

To determine previously administered COVID-19 doses, check medical records, immunization information systems, and vaccination record cards to help determine the initial product received. If the vaccine product for a primary mRNA dose cannot be determined or is no longer available, any available mRNA vaccine may be administered (separate doses by at least 28 days). If a different mRNA COVID-19 vaccine is inadvertently administered for the primary series or additional primary dose, the dose is considered valid, and no additional doses of either product are recommended.

Ages 5 through 11 years of age:
Pfizer-BioNTech (orange cap), 2-dose primary series

Ages 12 through 17 years of age:
Pfizer-BioNTech (purple cap/gray cap), 2-dose primary series followed by 1 booster dose.

Ages 18 and older:
Pfizer-BioNTech (purple cap/gray cap), 2-dose primary series followed by 1 booster dose

Moderna, 2-dose primary series followed by 1 booster dose

Janssen (Johnson & Johnson), 1-dose primary series followed by 1 booster dose

Immunocompromised Persons

See answers to question 3 to determine if an additional primary dose is recommended.

For people who received a COVID-19 vaccine outside the United States:

The recommendations for people vaccinated outside the United States depend on the vaccine(s) received for the primary series, whether the primary series was completed, and whether a booster dose was received. Current guidance can be found at: www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#appendix-e

3. Do you have a health condition or are you undergoing treatment that makes you moderately or severely immunocompromised?

COVID-19 vaccines may be administered to people with underlying medical conditions, such as HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies, who have no contraindications to vaccination.

VACCINE PRODUCT	Additional Primary Series Dosage (Amount)
Pfizer-BioNTech COVID-19 Vaccine *(Orange Cap)* 5 through 11 years of age	0.2 mL
Pfizer-BioNTech COVID-19 Vaccine *(Purple Cap or Gray Cap)* 12 years of age and older	0.3 mL
Moderna COVID-19 Vaccine	0.5 mL
Janssen COVID-19 Vaccine (Johnson & Johnson)	0.5 mL

Use of mRNA vaccines is preferred.

A 3-dose mRNA primary series is recommended for persons 5 years of age and older who are moderately or severely immunocompromised at the time of vaccination.

A primary Janssen vaccine dose may be administered to people ages 18 years and older who are moderately or severely immunocompromised, followed by a second (additional) dose using an mRNA COVID-19 vaccine

Booster doses are recommended for people 12 years of age and older after completion of the 3-dose primary series.

See "Interim COVID-19 Immunization Schedule for Ages 5 Years and Older" https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-5yrs-older.pdf

People who are immunocompromised should be counseled about the potential for a reduced immune response to COVID-19 vaccines and the need to continue to follow current prevention measures (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html) to protect themselves against COVID-19 until advised otherwise by their healthcare professional.

Additional information including immunocompromising conditions and treatments can be found in the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

4. Have you received a hematopoietic cell transplant (HCT) or CAR-T-cell therapy since receiving COVID-19 vaccine?

HCT and CAR-T-cell recipients who received doses of COVID-19 vaccine prior to receiving an HCT or CAR-T-cell therapy should be revaccinated with a primary vaccine series at least 3 months (12 weeks) after transplant or CAR-T-cell therapy. Additional information can be found at: Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

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5. Have you ever had an allergic reaction to:

- A component of a COVID-19 vaccine, including:
  - Polyethylene glycol (PEG)*, which is found in some medications, such as laxatives and preparations for colonoscopy procedures
  - Polysorbate, which is found in some vaccines, film-coated tablets, and intravenous steroids
- A previous dose of COVID-19 vaccine

People with a severe allergic reaction† to a previous COVID-19 vaccine dose or a known (diagnosed) allergy to a component of the vaccine have a contraindication to vaccination. People who had an immediate (< 4 hours), but non-severe allergic reaction to a previous dose of COVID-19 vaccine, have a precaution to receiving the same type of COVID-19 vaccine product. Although they can receive the same product, a different COVID-19 vaccine product can also be administered.

People with a contraindication to one type of COVID-19 vaccine (e.g., mRNA) should not receive any doses of that type of vaccine and have a precaution to the other type of vaccine (e.g., Janssen viral vector). People with a history of immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, have a precaution to vaccination with that COVID-19 vaccine, even if it is unknown which component elicited the allergic reaction.

COVID-19 Vaccine Components‡

Description	**Pfizer-BioNTech** mRNA COVID-19 Vaccine		**Moderna** mRNA COVID-19 Vaccine	**Janssen** COVID-19 Vaccine
	For 5-11 years formulation (Orange Cap) and 12 years and older formulation (Gray Cap)	For 12 years and older formulation (Purple Cap)		
Active ingredients	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2		Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive ingredients	2[(polyethylene glycol {PEG})-2000]-N, N-ditetradecylacetamide		PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine		1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol		Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate)		SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Tromethamine	Sodium chloride	Tromethamine	Sodium chloride
	Tromethamine hydrochloride	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Sucrose	Potassium chloride	Acetic acid	
		Dibasic sodium phosphate dihydrate	Sodium acetate	
		Sucrose	Sucrose	

* Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 Vaccine. Because PEG and polysorbate are structurally related, cross-reactive hypersensitivity between these compounds may occur.

† When vaccine recipients report a history of an immediate allergic reaction, providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as vasovagal reaction or postvaccination side effects (which are not contraindications to receiving the second of an mRNA COVID-19 vaccine dose).

‡ None of the vaccines contain eggs, gelatin, latex, or preservatives.

Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vaccination

In patients who experience post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of the vaccine. Additional information can be found at Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

Healthcare professionals should be familiar with identifying severe allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine administration. Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine. See Management of Anaphylaxis at COVID-19 Vaccination Sites for additional guidance. https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions. All people are recommended to be observed following COVID-19 vaccination for at least 15 minutes. Patients should be seated or lying down for vaccination and during the observation period to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

6. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or another injectable medication?

A history of any immediate allergic reaction (onset <4 hours of exposure) to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of COVID-19 vaccines) is a precaution to currently FDA-authorized or -approved COVID-19 vaccines. This also applies if the non-COVID-19 vaccine or therapy has multiple components, one or more of which is a component of a COVID-19 vaccine, and it is unknown which component elicited the allergic reaction. Vaccine may be given, but counsel patients about unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist should be considered. Considerations for vaccination include risk of exposure to SARS-CoV-2, risk of severe disease or death due to COVID-19, previous infection with COVID-19, unknown risk of anaphylaxis following COVID-19 vaccination, and ability of recipient to receive care immediately for anaphylaxis, if necessary. **These individuals should be observed for 30 minutes after vaccination.**

7. Clinical Considerations:

Response	Consideration
Male between 12 and 39 years of age	Males 5 through 17 years of age should receive the correct formulation of Pfizer-BioNTech COVID-19 vaccine. Males 18 and older can receive any FDA-authorized or -approved vaccine. People receiving mRNA COVID-19 vaccines, especially males ages 12–39 years, should be made aware of the rare risk of myocarditis and/or pericarditis following receipt of mRNA COVID-19 vaccines and the benefit of COVID-19 vaccination in reducing the risk of severe outcomes from COVID-19, including the possibility of cardiac sequelae. Counseling should include the need to seek care if symptoms of myocarditis or pericarditis, such as chest pain, shortness of breath, or tachycardia develop after vaccination, particularly in the week after vaccination. Extending the interval between the first and second mRNA vaccine dose to 8 weeks might reduce the risk. Additional recipient education materials can be found at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html.
History of myocarditis or pericarditis	■ Development of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine and subsequent doses should generally be avoided. ■ If after a risk assessment, the decision is made to receive a subsequent COVID-19 vaccine dose, the person should wait until after their episode has resolved. ■ For men ages 18 years and older who choose to receive a subsequent COVID-19 vaccine, a Janssen COVID-19 Vaccine can be considered instead of mRNA COVID-19 vaccines. ■ Persons who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination may receive any currently FDA-approved or -authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has resolved.
Had multisystem inflammatory syndrome; either MIS-C (children) or MIS-A (adults)	It is unknown if people with a history of MIS-C or MIS-A are at risk for a dysregulated immune response to COVID-19 vaccination. People with a history of MIS-C or MIS-A may choose to be vaccinated. Considerations for vaccination may include: ■ Clinical recovery from MIS-C or MIS-A, including return to normal cardiac function ■ Personal risk of severe acute COVID-19 (e.g., age, underlying conditions) ■ High or substantial community transmission of SARS-CoV-2 and personal increased risk of reinfection. ■ Timing of any immunomodulatory therapies (general best practice guidelines for immunization can be consulted for more information https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html) ■ It has been 90 days or more since their diagnosis of MIS-C ■ Onset of MIS-C occurred before any COVID-19 vaccination A conversation between the patient, their guardian(s), and their clinical team or a specialist may assist with COVID-19 vaccination decisions. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment Project at www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html.

Response	Consideration
Have a bleeding disorder	ACIP recommends the following technique for intramuscular vaccination in patients with bleeding disorders or taking blood thinners: a fine-gauge needle (23-gauge or smaller caliber) should be used for the vaccination, followed by firm pressure on the site, without rubbing, for at least 2 minutes.
History of thrombosis with thrombocytopenia syndrome (TTS)	It is contraindicated to administer Janssen COVID-19 Vaccine to persons with a history of TTS following receipt of the Janssen COVID-19 Vaccine or any other adenovirus vector-based COVID-19 vaccines (e.g., AstraZeneca's COVID-19 Vaccine) These persons should receive a dose of an mRNA COVID-19 vaccine as a booster dose at least 2 months (8 weeks) following their dose of the Janssen COVID-19 Vaccine and their clinical condition has stabilized. Prior to booster vaccination, a conversation between the patient and their clinical team, including hematologists or other specialists, may assist with vaccination decisions
History of heparin-induced thrombocytopenia (HIT)	With a history of an episode of an immune-mediated syndrome characterized by TTS, such as a spontaneous or classic HIT, should not receive Janssen COVID-19 Vaccine. These persons should receive a current FDA-authorized or -approved mRNA COVID-19 vaccine
Take a blood thinner	People who regularly take aspirin or anticoagulants as part of their routine medications do not need to stop these medications prior to receipt of any COVID-19 vaccine
History of Guillain-Barré Syndrome (GBS)	■ A history of GBS, either before or after COVID-19 vaccination, is a precaution for receipt of Janssen COVID-19 Vaccine. An mRNA vaccine is preferred. ■ Persons who develop GBS within 6 weeks of Janssen COVID-19 vaccination should only receive an mRNA COVID-19 vaccine for subsequent doses.